



Food and Drug Administration
Rockville MD 20857

Re: Zometa
Docket No.: 02E-0020

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

JAN 21 2003

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 4,939,130, filed by Novartis Corporation, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Zometa, the human drug product claimed by the patent.

The total length of the regulatory review period for Zometa is 2,901 days. Of this time, 2,292 days occurred during the testing phase and 609 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 12, 1993.

The applicant claims September 18, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 12, 1993, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: December 21, 1999.

FDA has verified the applicant's claim that the new drug application (NDA) for Zometa (NDA 21-223) was initially submitted on December 21, 1999.

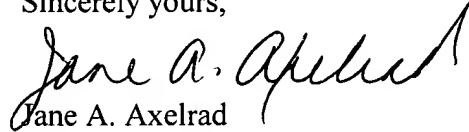
3. The date the application was approved: August 20, 2001.

FDA has verified the applicant's claim that NDA 21-233 was approved on August 20, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jane A. Axelrad". The signature is fluid and cursive, with a large, sweeping initial "J".

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Thomas Hoxie
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